

SUPPLEMENTARY INFORMATION: Macleod Pharmaceuticals, Inc., 2600 Canton Ct., Fort Collins, CO 80525, is the sponsor of ANADA 200-115, which provides for the use of a generic gentamicin solution (100 milligrams/milliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

Approval of ANADA 200-115 for Macleod Pharmaceuticals' gentamicin sulfate solution (100 mg/mL gentamicin) is as a generic copy of Schering's Gentocin® Solution (100mg/mL gentamicin) in NADA 046724. The ANADA is approved as of July 21, 1995, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 529

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.1044a [Amended]

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended

in paragraph (b) by removing “000061, 057561, and 000856” and adding in its place “000061, 000856, 057561, and 058711”.

Dated: August 14, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95-21455 Filed 8-29-95; 8:45 am]

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

Office of the Assistant Secretary for Community Planning and Development

24 CFR Part 91

[Docket No. FR 3611-F-10]

Consolidated Submission for Community Planning and Development Programs

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Final rule.

SUMMARY: As part of HUD's effort to consolidate and streamline submission requirements for the four formula grant programs, the Department published in the **Federal Register** on January 5, 1995, a final rule that consolidated into a single submission the planning and application aspects of the Department's Community Development Block Grant (CDBG), Emergency Shelter Grant (ESG), HOME Investment Partnerships (HOME), and Housing Opportunities for Persons with AIDS (HOPWA) programs. The purpose of this rule is to make an amendment to the deadline for submission of the Consolidated Plan in order to receive Community Development Block Grant funds.

EFFECTIVE DATE: September 29, 1995.

FOR FURTHER INFORMATION CONTACT:

James R. Broughman, Director, Office of Block Grant Assistance, Office of Community Planning and Development, 451 Seventh Street, SW., Washington, DC 20410-7000, telephone (202) 708-3587 (voice) or (202) 708-2565 (TDD). (These are not toll-free numbers.) Copies of this amendment will be made available on tape or large print for those with impaired vision that request them. They may be obtained at the above address.

SUPPLEMENTARY INFORMATION: On January 5, 1995 (60 FR 1878), the Department published in the **Federal Register**, a final rule that consolidated into a single submission the planning and application aspects of the

Department's Community Development Block Grant (CDBG), Emergency Shelter Grant (ESG), HOME Investment Partnerships (HOME), and Housing Opportunities for Persons with AIDS (HOPWA) programs. The purpose of this rule is to make an amendment to the deadline for submission of the Consolidated Plan in order to receive Community Development Block Grant funds.

The regulation requires jurisdictions to align the program years for the four formula programs and to submit the Consolidated Plan 45 days before the start of the program year instead of the 30 days previously recommended for submission of the CDBG Final Statement. The final date for submission of all Consolidated Plans was established as August 16. The final date previously established for submission of all CDBG final statements had been the first working day in September. To provide maximum flexibility during this transition period, HUD is amending the Consolidated Plan rule to permit the submission of the Consolidated Plan for Fiscal Year 1995 to be made not later than September 30, 1995.

Justification for Final Rulemaking

HUD generally publishes a rule for public comment before issuing a rule for effect, in accordance with its own regulations on rulemaking at 24 CFR part 10. However, part 10 provides that prior public procedure will be omitted if HUD determines that it is “impracticable, unnecessary, or contrary to the public interest” (24 CFR 10.1).

In this case, HUD finds that publishing this rule providing for a new consolidated plan deadline for FY 1995 for public comment would be impracticable and contrary to the public interest. Maximum flexibility in submitting consolidated plans during this first year of transition following publication of the final rule establishing the consolidated plan is in the public interest. The time necessary to allow for public comment would preclude the possibility of making the rule effective before the extended deadline date of September 30, 1995. It would be impracticable, therefore, to extend greater flexibility to grantees if a public comment period was provided before the rule takes effect.

Other Matters

Executive Order 12866

This final rule was reviewed by the Office of Management and Budget (OMB) under Executive Order 12866 on Regulatory Planning and Review, issued by the President on September 30, 1993.

Any changes made in this final rule as a result of that review are clearly identified in the docket file, which is available for public inspection in the office of the Department's Rules Docket Clerk, Room 10276, 451 Seventh Street, SW., Washington, DC.

Environmental Impact

A Finding of No Significant Impact with respect to the environment was made in accordance with HUD regulations at 24 CFR part 50, which implement section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332) in connection with the development of the January 5, 1995 rule. The Finding of No Significant Impact remains applicable to this rule, and is available for public inspection and copying Monday through Friday, 7:30 a.m. until 5:30 p.m. in the office of the Rules Docket Clerk, Office of General Counsel, room 10276, 451 Seventh Street, SW., Washington, DC 20410.

Regulatory Agenda

This rule was not listed in the Department's Semiannual Agenda of Regulations published on May 8, 1995 (60 FR 23368) in accordance with Executive Order 12866 and the Regulatory Flexibility Act.

Executive Order 12612, Federalism

The General Counsel, as the Designated Official under section 6(a) of Executive order 12612, Federalism, has determined that the policies contained in this rule do not have federalism implications and, thus, are not subject to review under the Order. The change made by this rule increases flexibility for jurisdictions during the FY 1995 transition year.

Executive Order 12606, The Family

The General Counsel, as the Designated Official under Executive Order 12606, The Family, has determined that this rule does not have a potential significant impact on family formation, maintenance, and general well-being, and, thus, is not subject to review under the Order. No significant change in existing HUD policies or programs, as those policies relate to family concerns, will result from promulgation of this rule.

List of Subjects in 24 CFR Part 91

Grant programs—Indians, Homeownership, Low and moderate income housing, Public housing.

Accordingly, 24 CFR part 91 is amended as follows:

PART 91—[AMENDED]

1. The authority citation for part 91 continues to read as follows:

Authority: 432 U.S.C. 3535(d), 3601–3619, 5301–5315, 11331–11388, 12701–12711, 12741–12756, and 12901–12912.

2. In § 91.15, paragraph (a)(2) is amended to read as follows:

§ 91.15 Submission date

(a) * * *

(2) In no event will HUD accept a submission earlier than November 15 or later than August 16 of the Federal fiscal year for which the grant funds are appropriated, except for Fiscal Year 1995 in which HUD will accept a submission no later than September 30, 1995. (Failure to submit the plan by August 16 will automatically result in a loss of the CDBG funds to which the jurisdiction would otherwise be entitled, except for Fiscal Year 1995).

* * * * *

Dated: August 25, 1995.

Kenneth C. Williams,

Deputy Assistant Secretary for Grant Programs.

[FR Doc. 95–21587 Filed 8–29–95; 8:45 am]

BILLING CODE 4210–29–P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD02–95–011]

RIN 2115–AE46

Special Local Regulations; Ducks on the Ohio; Ohio River Mile 792.0–793.0

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: A special local regulation is being adopted for the Ducks on the Ohio which will be held on the Ohio River near Evansville, Indiana on September 9, 1995. This regulation is needed to control vessel traffic in the immediate vicinity of the event. The regulation will restrict general navigation in the regulated area for the safety of spectators, participants and through traffic.

EFFECTIVE DATE: This regulation is effective from 1 p.m. to 4 p.m. local time on September 9, 1995.

FOR FURTHER INFORMATION CONTACT: LCDR J.O. Jaczinski, Chief, Boating Affairs Branch, Second Coast Guard District, 1222 Spruce Street, St. Louis, Missouri 63103–2832. The telephone

number is (314) 539–3971, fax (314) 539–2685.

SUPPLEMENTARY INFORMATION:

Drafting Information

The drafters of this regulation are LCDR J.O. Jaczinski, Project Officer, Second Coast Guard District, Boating Safety Division, and LT S. Moody, Project Attorney, Second Coast Guard District Legal Office.

Regulatory History

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impracticable. Specifically, the sponsor's late submission of the regatta application left insufficient time to publish a notice of proposed rulemaking in advance of the scheduled event. The Coast Guard deems it to be in the public's best interest to issue a regulation immediately.

Background and Purpose

The Ducks on the Ohio consists of a duck race. The show will begin at 1 p.m. local time on September 9, 1995 and will end at 4 p.m. local time. In order to provide for the safety of spectators and participants, and for the safe passage of through traffic, the Coast Guard will restrict vessel movement in the regulated area. The river will be closed during part or all of the effective period to all vessel traffic except official regatta vessels and patrol craft. These regulations are issued pursuant to 33 U.S.C. 1233 and 33 CFR 100.35.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary because of the event's short duration.

Federalism Assessment

The Coast Guard has analyzed this action in accordance with the principles and criteria of Executive Order 12612 and has determined that this regulation does not raise sufficient federalism